

## REMARKS

The withdrawal of the objection to the specification has been noted. Claim 10 has been amended to correct the informality that was pointed out by the Examiner. The amended text of claim 10 conforms to the Examiner's interpretation as set forth at page 3 of the Office Action.

Claims 8 and 10-13 have been finally rejected under 35 U.S.C. §103(a) as being unpatentable over Lieberman in view of Ullman et al. (Ullman) and Geller.

Reconsideration is requested.

Lieberman was cited as teaching a pharmaceutical tablet with layers and that it is known to have a tablet wherein the center is free of active. Lieberman was also cited as teaching that it is known to place scores on tablets to allow for manual breakage. The Examiner acknowledged that Lieberman did not "directly teach" a tablet with only two layers or the location of the score or of the active ingredient.

The Examiner did not acknowledge that the portion of Lieberman that was relied upon for the teaching of the three-layer tablet was on page 274 while page 172 of Lieberman was also the section cited for its teaching that the purpose of a score was to permit breaking the tablet into equal parts for administration of a half a tablet. If it were his intent to teach breaking a three-layer tablet, he would not have addressed this issue in sections of his book that were 102 pages apart. There is no nexus between the section describing the three-layer tablet (for purposes of keeping incompatible drugs apart from one another by providing those actives in separate layers of a single tablet) and the section describing scoring of tablets to facilitate breaking. There is no teaching or suggestion in Lieberman that the three-layer tablet can be divided (whether scored

or unscored) in a way that provides, following division, each active in a discrete portion of the tablet).

It also would not be consistent with a teaching regarding "breaking into equal parts" because unless the break took place in the inert portion of the tablet (which he doesn't teach), the break of the three-layer tablet would not necessarily result in equal parts. Thus, the Lieberman teaching regarding scoring a tablet is unconnected with the Lieberman disclosure of a three-layer tablet and there is no teaching that the three-layer tablet should be scored or that every tablet should be scored.

The secondary reference of Ullman was then applied as teaching a multi-fractionable unitary structure. No contention has been raised that Ullman in any way teaches or suggests a two-layered tablet because Ullman discloses only a single layer or homogeneous tablet structure. Geller was applied as teaching deeply scored tablets (up to 66% of the entire tablet) wherein the active ingredient is isosorbide. Geller was also cited as recognizing the deficiency in scored tablets i.e. "scores do not always assure precise division of the tablet". It should be noted that Geller, while acknowledging the problem of imprecise tablet splitting, does not suggest any solution involving a second inert layer.

The different considerations that arise from the breaking of a layered tablet versus the breaking of an unlayered tablet point to the unobviousness of the claimed invention as compared to the different concepts set forth in Lieberman, Ullman and Geller. Each of the cited references describes tablet structures that are made differently for different purposes. The concept of the present invention is not found in any of the cited references.

On pages 8 and 9 of the Office Action, the Examiner opined that "it would have been obvious to one of ordinary skill in the art at the time that the invention was made,

that upon identification of the benefits of the trilayer scored tablet, one would clearly desired the same feature (reduced breakage through active layer) to avoid dosage variation when delivering only one active".

This argument does not explain where Lieberman disclosed that there is "reduced breakage through the active layer". A diligent review of Lieberman has not revealed any mention by Lieberman that reduced breakage is a benefit that flows from his three-layered tablets. It is the applicants' position that any benefit from breaking the two-layered tablet is only found in the applicants' specification. This fact should be apparent to the casual observer as the Lieberman, Ullman and Geller references do not disclose any two-layered tablet.

The argument that one would remove one of the drug layers of the Lieberman three-layer tablet in order to deliver only one of the actives does not address the fact that no one who is skilled in the art would make a two-layered tablet with one inactive layer, as claimed, by removal of one active layer.

If one active is desired, one would make a single-layer, homogeneous tablet and no one would attempt to deconstruct the Lieberman tablet if only one active was to be made. Once the active layer is formed, there is no need to add a second, inactive layer except to provide a layer which facilitates accurate breaking of the tablet, which is the concept taught only by the claimed invention. Forming a three-layer tablet having two actives, then removing one of the actives would be contraindicated in any process carried out by a person of ordinary skill in the art because such deconstruction requires unnecessary and inefficient process steps.

It can be readily appreciated and understood from the present application, that breaking the tablet through the inert layer provides for very accurate breaking of a tablet.

This information cannot be used to modify what is taught in the prior art as it reflects the applicants' contribution. The cited prior art does not disclose a two layer-scored tablet as defined in claim 8 where the score extends at least 70% of the distance into the active layer.

The present rejection is not based on the contents of the cited reference. No explanation has been given as to where in the references any disclosure is found that tells the skilled artisan to keep a separating layer on a tablet when the reason for its presence no longer exists because there is no incompatible third layer.

It is a fundamental concept in patent law that isolated teachings may not be extracted from a reference and combined with unsupported contentions as to what a skilled person in the art would be motivated to do. In the present case, the prior art used the inert layer for one purpose and only one purpose, namely to separate incompatible active drugs. Since claim 8 excludes any incompatible layer, there is no reason that supports the argument that Lieberman provides a direction or motivation to deconstruct the three-layer tablet and retain one active layer with the inert layer.

In presenting the case for obviousness, the Examiner has relied on the decision that was made in *Ex parte Wu*, 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989). That case involved method claims that were directed to a method for inhibiting corrosion on metal surfaces using a composition consisting of epoxy resin, petroleum sulfonate, and hydrocarbon diluent. The claims were rejected over a primary reference which disclosed an anticorrosion composition of epoxy resin, hydrocarbon diluent, and polybasic acid salts wherein said salts were taught to be beneficial when employed in a freshwater environment, in view of secondary references which clearly suggested the addition of petroleum sulfonate to corrosion inhibiting compositions. The Board affirmed the

rejection, holding that it would have been obvious to omit the polybasic acid salts of the primary reference where the function attributed to such salt is not desired or required, such as in compositions for providing corrosion resistance in environments which do not encounter fresh water. In the present case, the claims are directed to a pharmaceutical tablet having two layers where the primary reference was concerned with a three-layer tablet.

The Wu obviousness analysis does not teach or suggest the removal or extraction of a component from a composition in order to make a composition where a component was to be omitted. The Wu analysis was based on the elimination of a component when the composition was first formulated, when there was no reason to retain the component in the composition once a decision was made to use the composition in a different environment. What actually would be done according to Wu, is that one would reformulate and use only the necessary ingredients. The ingredients would be mixed and one would leave out the unnecessary component and would not consider removal of an ingredient from a mixed composition.

When this analysis is applied to the making of a tablet having a single active ingredient and Lieberman is used as a guide for making the single active ingredient tablet, one would not remove a section from the three-layer tablet to make a tablet having one active ingredient. Under Wu, if a component is not desired or required, one would not deconstruct the three-layered tablet but rather one would start with tablet making ingredients and make a tablet with one active ingredient. Furthermore, since a useless inert layer would not be desired or required, the inert layer would not be added after the single active ingredient tablet was made. In other words, if a single active ingredient is desired in a tablet, one would not even consider Lieberman to be pertinent prior art as it does not deal with the tableting of single active ingredients.

Claim 8 points out a tablet which is distinguishable from Lieberman, Ullman and Geller because claim 8 points out a scored tablet having two segments, one of which has no active ingredient and has a score in the active segment where the score extends at least 70% of the distance to the second segment. This concept is not disclosed or suggested by Lieberman, Ullman or Geller as the tablets disclosed by these references are either three-layer tablets or one layer tablets.

The language of claim 8, part (a) points out the claimed tablet consists of two segments which excludes the three-layered tablets of Lieberman who does not make a two-layered tablet obvious. Geller is only concerned with a single layer tablet and does not disclose the benefit of being able to break a tablet where there is a deeply scored active layer and an inert lower layer which results in a more equal division of the active component.

As noted above, Claim 8 and the claims that are dependent on claim 8 point out a structure where there are two segments, one of which is inactive and there is a minimum distance into the active layer for the score, where the distance is specified as being at least 70% of the distance from the top surface to the interface between the two segments. There is no reason to modify Lieberman with the Geller score technique because Geller is concerned with making a single layer tablet with one active ingredient and does not suggest a two-layered tablet where the score is a minimum of 70% of the distance from the top of the tablet to a second inert segment. If one were to deeply score the Lieberman tablet, one would not obtain the benefits of the deep score taught by Geller. This is evident from the fact that in a three-layer tablet, the presence of a deep score would have no effect on the third layer based on the Geller teaching that the score should not extend more than 2/3 of the way through the tablet which in the case of the Lieberman

tablet, would not allow the break to occur in the inactive layer.

Attached to this Amendment is the Declaration of Elliot Hahn which is being filed under the provisions of 37 CFR§1.132 to provide the results of actual tests which recorded the relative accuracy obtained when tablets according to the present invention were broken and when prior art scored tablets were broken. The tests were evaluated by weighing the tablets after they were broken by hand. The tests showed that the tablets of the present invention had a maximum deviation, between tablet halves, that was below 3.5%. In the case of prior art scored tablets, the deviation was observed to be as high as 20% for certain tablets and in addition, 55 of the 90 prior art test tablets could not be split by the volunteer testers while all of the tablets of the invention could be split by the volunteers. These results validate the concept of the invention and these results could not be predicted from any disclosure in Lieberman, Ullman or Geller. For these reasons, it is requested that this ground of rejection be withdrawn.

Claims 8-12 were provisionally rejected for obviousness double patenting over copending application Serial No. 10/598,355.

A terminal disclaimer will be filed upon the indication of allowable subject matter to obviate the provisional double patenting rejection.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'J. Costigan', is positioned above the printed name.

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